UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,460	06/14/2006	Thomas Mann	PAT 992W-2	6904

26123 7590 09/29/2008

BORDEN LADNER GERVAIS LLP
Anne Kinsman
WORLD EXCHANGE PLAZA
100 QUEEN STREET SUITE 1100
OTTAWA, ON K1P 1J9
CANADA

EXAMINER	
AFREMOVA, VERA	
ART UNIT	PAPER NUMBER
1657	

NOTIFICATION DATE	DELIVERY MODE
09/29/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipinfo@blgcanada.com
aarmstrongbaker@blgcanada.com
akinsman@blgcanada.com

Office Action Summary	Application No.	Applicant(s)	
	10/596,460	MANN ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *14-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/18/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the group (claims 1-13) in the reply filed on 6/20/2008 is acknowledged.

Claims 14-22 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected invention(s), there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 6/20/2008.

Claims 1-13 are under examination in the instant office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 3 and 7-13 rejected under 35 U.S.C. 102(b) as being anticipated by US 6,143,555 (Kusunoki et al).

Claims are directed to a method of identifying a microorganism comprising the steps of a) obtaining a test sample of an unknown microorganism; b) adding a mediator or mediator mixture to the test sample in the presence of an effector; c) assessing variation in respiration rate of the microorganism over a pre-determined time period; and d) comparing the variation in the respiration rate of the microorganism with the variation in respiration rates of known

microorganisms exposed to the effector, thereby, identifying the unknown microorganism in the test sample.

Some claims are further drawn to the mediator being a generic oxidant and to effector being sugar or glucose, fructose, etc. Some claims are further drawn to assessment of respiration rates of microorganisms using electrochemical measurements or biamperometric. Some claims are further drawn to the assessment time for 15 minutes.

US 6,143,555 (Kusunoki et al) teaches a method of identifying an unknown microorganisms by measuring respiration rates of the unknown and known microorganisms in multiple media and comparing the respiration variation rate values between unknown and known microorganisms, thereby, identifying the unknown microorganisms (entire document including abstract). Thus, the cited comprising identical steps as required by the claimed method including steps of a) obtaining a test sample of an unknown microorganism; b) adding a generic mediator to the test sample in the presence of a generic effector; c) assessing variation in respiration rate of the microorganism over a pre-determined time period; and d) comparing the variation in the respiration rate of the microorganism with the variation in respiration rates of known microorganisms exposed to the same effector, thereby, identifying the unknown microorganism in the test sample.

The respiration rates of microorganisms are assessed by measuring electric current created by microbial metabolic activities or they are measured electrochemically or amperometrically (figures 3-5). The measuring time include interval of 15 minutes (figures 3-5). The generic mediator and effector in the cited method would be generic components of buffer

solutions and/or microbiological media include oxidants or vitamins of yeast extract and sugars or effector such as glucose (col. 5, lines 55-57).

Therefore, the cited patent US 6,143,555 (Kusunoki et al) is considered to anticipate the instant invention as presently claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,143,555 (Kusunoki et al) taken with US 6,391,577 (Mikkelsen et al) and US 4,528,270 (Matsunaga).

Claims are directed to a method of identifying a microorganism comprising the steps of a) obtaining a test sample of an unknown microorganism; b) adding a mediator or mediator mixture to the test sample in the presence of an effector; c) assessing variation in respiration rate of the microorganism over a pre-determined time period; and d) comparing the variation in the respiration rate of the microorganism with the variation in respiration rates of known microorganisms exposed to the effector, thereby, identifying the unknown microorganism in the test sample. Some claims are further drawn to the step of adding a mediator or mediator mixture to the test sample that comprises combining the test sample with a solution of the effector for a fixed time prior to adding the mediator. Some claims are further drawn to the mediator being an

oxidant. Some claims are further drawn to the mediator being ferricyanide, dichlorophenol-indophenol (DCIP), ferrocene and ferrocene derivatives, methylene blue, janus green, tris(bipyridyl)iron(III), a quinine (benzoquinone, naphthoquinone, menadione or anthraquinone) or a phenazine (phenazine methosulfate or phenazine ethosulfate). Some claims are further drawn to assessment of respiration rates of microorganisms using electrochemical measurements and to the electrochemical measurements that are biamperometric or coulometric. Some claims are further drawn to the assessment of respiration rates of microorganisms by the electrochemical measurement of mediator consumption, to the assessment of respiration rates for the pre-determined time period of up to 15 minutes. Some claims are further drawn to the use of microorganisms in an arrested growth state. Some claims are further drawn to the assessment of respiration rates with a plurality of effectors separately. Some claims are further drawn to the use of effector(s) selected from the group consisting of succinate, D-xylose, D-lactose, ornithine, alpha-ketoglutarate, beta-glycerophosphate, D-fructose, sucrose, L-lysine, lactic acid, L-arginine, D-sorbitol, formic acid, L- tryptophan, D-galactose, L-rhamnose, D-arabinose, pyruvic acid, citric acid, malonic acid, D-mannose, beta-cyclodextrin, nitrate and glucose.

US 6,143,555 (Kusunoki et al) teaches a method of identifying an unknown microorganisms by measuring respiration rates of the unknown and known microorganisms in multiple media and comparing the respiration variation rate values between unknown and known microorganisms, thereby, identifying the unknown microorganisms (entire document including abstract). The respiration rates of microorganisms are assessed electrochemically or amperometrically by measuring electric current created by microbial metabolic activities (figures 3-5). The measuring time include interval of 15 minutes (figures 3-5). The generic mediators and

effectors are generic components of buffer solutions and/or microbiological media (col. 5, lines 55-57). Thus, the cited method is lacking disclosure about the use of specific mediators as required by the claimed inventions.

However, US 6,391,577 (Mikkelsen et al) teaches method comprising electrochemical detection of microorganisms using mediators such as ferricyanide, dichlorophenol-indophenol (DCIP), ferrocene and ferrocene derivatives, methylene blue, janus green, tris(bipyridyl)iron(III), a quinine (benzoquinone, naphthoquinone, menadione or anthraquinone) or a phenazine (phenazine methosulfate or phenazine ethosulfate), for example: see entire document , abstract and col. 5, lines 5-20. The disclosed effector(s) are selected from the group consisting of succinate, glucose, etc. (col. 7, lines 10-15). Measuring time is 15 minutes (col. 7, lines 15). The method of US 6,391,577 (Mikkelsen et al) is intended for assaying drug cytotoxic effect on microorganisms and it is not intended for identifying unknown microorganisms by comparing electrical current values created by metabolic activities of unknown and known microorganisms.

However, US 4,528,270 (Matsunaga) teaches and/or suggest the use of values of pick current potentials created by metabolic activities of individual microorganisms to distinguish between various types of microorganisms and/or to distinguish between unknown and known microorganisms (entire document including abstract and col. 12, lines 1-15).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use specific mediators of microbial electron transfer disclosed by US 6,391,577 (Mikkelsen et al) in the method of identifying microorganisms based on comparing metabolic respiration rates by electrochemical assessments disclosed by US 6,143,555 (Kusunoki et al) with a reasonable expectation of success in comparing metabolic

activity and, thus, identifying microorganisms because pick current potentials created by metabolic activities of individual microorganisms can distinguish between various types of microorganisms as taught and/or suggested by US 4,528,270 (Matsunaga).

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

September 19, 2008

VERA AFREMOVA

PRIMARY EXAMINER

/Vera Afremova/
Primary Examiner, Art Unit 1657